Selling Honey in Pennsylvania

Honey is regulated by the Bureau of Food Safety which is part of the PA Department of Agriculture (PDA)

Laws Affecting Sale of Honey:

- 1. "Honey Sale and Labeling" Act 184 of 1974 (3 Pa. C.S.A. §§ 311 318)
- 2. Chapter 57- Food Protection.
 - "Retail Food Facility Safety Act" (3 Pa. C.S.A. §§ 5701 5714)
 - "Food Safety Act" (3 Pa. C.S.A. §§ 5721 5737)
- 3. Code of Federal Regulations (21 CFR 117)

Exemption:

House Bill 2565 – Amends Act 106 to exempt retail food facilities from licensing requirements and food establishments from registration if they are in compliance with the Act of July 20, 1974 (P.L. 537, No 184) referred to as the Honey Sale and Labeling Act, and in which 100% of the regulated product offered for human consumption are produced or processed "on the farm" on which the retail food facility or the food establishment are located.

General Guidelines:

1. If honey is produced, processed, and sold on the same farm:

- The honey producer is exempt from **both** the retail food facility and the food establishment licensing/registration requirements.
 - **No applications are required, and no fees are paid**. However, while NOT in the food safety "system", the honey producer is still subject to inspections if warranted (e.g. complaints, foodborne illness and outbreak investigations, etc.).

Notes:

- If NO fee is paid, there is NO registration issued. The Law exempts the on-farm honey processer from a fee but not potential inspection. The Food Safety Inspector is not inspecting honey processors that are only selling on farm, but Food Safety Inspectors are inspecting honey processors that sell their honey off premises or sell to other businesses.
- The application is filed so the honey producers are entered into the Food Safety data base, and the Food Inspectors can do the inspections. It also assures if another local health inspector in other jurisdictions finds the product for sale, PDA can affirm that it is from an inspected approved source.

Frequently Asked Questions:

1. What if I raise, process and sell my honey on site ("farm"), but I need to buy in and sell another beekeeper's honey to keep up with the demand for honey? It is PA honey and I bottle it on my farm.

You will need to register with Food Safety, pay the \$35 registration fee, and you will be inspected. You are not exempt because the honey is not 100% produced and processed on the same site.

2. I have well water. Since I do not use water in the production of the honey, just for the cleanup, can I buy and use bottled water rather than getting my well water tested (which costs a fair amount of money)?

Food Safety's Response:

While you may not use water in the production of the product, you will use it for handwashing and cleaning equipment, so a safe, potable water source is necessary. While it is possible to use an alternate water source for production under the LFE license, a handwash set up with continuous flow of hot and cold water is required; therefore, it is often less expensive and cumbersome to use your well water. Well water should be tested initially for nitrates, nitrites and coliform and is not very expensive.

3. What if I sell other food products grown on my farm?

This does **NOT** exempt you from any other Food Safety Rules and Regulations. It only applies to honey. You must follow the Food Safety Rules for other products as appropriate. Other foods that would not require registration or inspection are raw agricultural commodities (RACs). Any processing of foods is not exempt.

4. What if I am selling my honey in another state?

You **MUST** register with Food Safety.

You **MUST** pay the \$35 registration fee.

You **WILL** be inspected by a Food Safety Inspector about every 24 months.

5. What if I belong to a club and we have a shared extracting site (honey house) that many members use?

The site **MUST** be registered, and the \$35 Food Safety Registration fee **MUST** be paid.

Although the "club or organization" can be listed as the "owner" on the registration, the name of an actual PERSON, who is responsible for the honey house operation (perhaps the club president) must be listed with the owner information. The beekeepers that come to that site do NOT need to register but must be able to show that honey was processed there through some type of recordkeeping.

The owner/operator should keep a log with names and dates of beekeepers extracting honey at that site.

The honey must be processed and stored at the same honey house until transported to a retail location. In this situation one registration to the site can be issued in lieu of each farmer being registered. If a honey

'farmer' is storing product at a location different than the registered establishment, that storage location must be registered as a food establishment/ warehouse as well.

6. What if honey is made and processed on the "farm", and then wholesaled?

You **MUST** register with Food Safety.

You do **NOT** have to pay the \$35 registration fee.

You **WILL** be inspected by a Food Safety Inspector about every 24 months.

7. What if a beekeeper gives or sells his or her honey to family or friends? The family or friends then sell the honey to someone else. The beekeeper may or may not know that this is being done. Which rules apply in this situation? Is the original beekeeper liable for any problems?

Honey given to family and friends, should be intended to be used for their own personal use. If the product is resold in anyway then the honey processor should be registered. If the honey processor is concerned this is happening, they may want to label their product "Not for Resale" to avoid an unregistered, unapproved food source from entering commerce.

8. What if I want to have the statement, "Reg. Penna. Dept. Agr." or the "PA Preferred" on my honey bottle?

You **MUST** register with Food Safety.

You **MUST** pay the \$35 registration fee.

You **WILL** be inspected by a Food Safety Inspector.

9. What is PA Preferred?

PA Preferred is a state-supported agricultural marketing program. The Pennsylvania Department of Agriculture launched the PA Preferred program to identify and promote food and agricultural products grown, produced and processed in Pennsylvania.

Please see the PA Department of Agriculture's website (https://www.agriculture.pa.gov), the PA Preferred website (https://www.agriculture.pa.gov), or call (717)-705-9511 for additional information.

"Every application has a story...." and each product and producer will be evaluated to determine eligibility. Sometimes even if 100% of a beekeeper's honey is NOT made by the bees while they are in PA, they will qualify. So, if you have questions, please contact someone in this division.

10. What are the benefits of being a PA Preferred member?

It promotes PA agriculture.

It is FREE.

It can be used as a marketing tool to help with sales.

Many Pennsylvanians want to buy and use local products.

11. What should be on a PA honey or pollen label?

- Common name (example: Honey or Pollen).
- Ingredients list (only necessary if more than a single ingredient.)
- Name and address of Manufacturer/Distributer
- Net weight of the honey or pollen

Common Name:

Honey is the common name and it is a single ingredient, so label should say "HONEY". If the food is a blend or a mixture of honey and another sweetener (e.g. corn syrup, sugar, flavor, etc.), the name must be sufficiently described on the label to distinguish it from simply "honey" (see 21 CFR 102.5(a)) and the facility <u>must register</u> as a processor with Food Safety, pay a \$35 registration fee, and be inspected.

For example, the name must say "Blend of honey and corn syrup" if the food has more honey than corn syrup (conversely, "Blend of corn syrup and honey" if the food has more corn syrup than honey).

If the food consists of honey and a flavor ingredient such as natural raspberry flavor, the name must say "raspberry-flavored honey"

Please refer to the "Guidance for Proper Labeling of Honey and Honey Products" on FDA website.

o Address of the processer or distributer:

If from extracting site used by others, enter "code" or date of extraction too.

There must be enough of an address so that the site could be found using a public search.

- -Business Example: Bees' Gold, Harrisburg, PA
- Individuals' Example: John and Jane Beekeeper, Main Street, Harrisburg, PA (or PO Box 1, Harrisburg, PA)

o Other information:

-You may wish to put "Do not feed to infants under 1 year of age" on your label, but it is not required. Infant botulism is caused by *Clostridium* bacteria which thrive in soil and dust. This can also contaminate certain foods, including honey.

Symptoms and signs of infant botulism include muscle weakness, poor sucking, a weak cry, constipation, and floppiness -decreased muscle tone. Even pasteurized honey can contain viable botulism spores because the honey must be boiled to kill the spore. Because of this, infants under 1 year should not eat food with honey listed as an ingredient, even if the food is cooked. The intestines usually contain enough acid in people over 1 year of age to destroy any toxins produced by botulism bacteria found in honey.

- -PA does **NOT** require labels on honey or pollen containers to have an expiration or best by date on the label.
- -The label does not need to say the location that the honey was made (as in made by the bees).

12. Important to remember:

Do **NOT** make claims that honey or pollen will absolutely cure specific or nonspecific diseases, problems, etc. unless you are registered with the Food and Drug Administration and they have approved these statements! Honey and pollen are not registered as a "drug".

13. I keep my bees in Town A, PA but I process the honey from them in Town B, PA. Is it a problem if I put my business name & Town A, PA on my label but add a sticker saying it was processed in Town B, PA? Basically, I don't want people to see the label & assume that I keep the bees in Town B, & not in Town A. Someone told me that they are pretty sure I can't have Town A on the label, but to me, as long as I include the address where it is processed, it doesn't seem like it would matter. Help!

The name and address of the processor or distributor does not need to be the location of the processing site. It could be a corporate or a headquarters' address.

For example, all the Hershey chocolate bars say Distributed by Hershey Chocolate Company, Hershey, PA, but very little of the product is actually made in Hershey, PA. It could be made anywhere in the world even. They have plants in Mexico and Canada but if you give them the lot code from a candy bar, they can tell exactly what processing facility the product was from. We may not know by looking at the code, but as long as a competent person at the labeled address can answer that question, it meets the labeling requirements.

Basically, the beekeeper can use any name and address they want, as long as it leads us to them as the owner and they can tell us where the product was processed. They also do not need to distinguish which honey bee colony product came from either, unless they want to do that for a traceback purpose of their own.

14. What should I expect from a Food Safety Inspection?

Inspectors prefer to conduct the inspection while extracting is occurring. Inspectors like clean, unbroken equipment.

Inspectors may or may not call first.

Inspectors will usually leave a business card if no one is on site.

Inspections will usually last 15 minutes or more.

15. My honey house was recently inspected. The Food Safety Inspector asked me questions about lot numbering, tracking, and written plans. These questions did not show up on the inspection report given to me. Is this a PA Department of Agriculture (PDA) or a Food and Drug Administration (FDA) regulation? Should I be doing something else in my record keeping? Some of these questions have to do with PDA's compliance with the Manufactured Food Regulatory Program Standards from the FDA. Those standards require PDA to maintain information on a firm's type of food products, size, geographic distribution, and food safety systems in place to assess potential public health risk, assign inspection frequencies, and target educational materials and outreach.

Other questions are related the Preventative Control Rules for Human Food (PC Rule), which by Law, PDA

has adopted as PA regulation for Food Establishments. The PC Rule did update and make changes to the current good manufacturing practices, basic sanitation and food safety standards as set forth in 21 CFR 117 Subparts B (see additional information in response to Q.16 below).

The biggest changes in the PC Rule relate to requirements for trained staff, formal and comprehensive written food safety plans, and associated recordkeeping.

The questions you were asked about lot numbering, tracking, and written plans are included in the facility record in the PDA data base for your honey house.

If you do not know the answers to these questions when the Food Safety Inspector asks, it is perfectly fine to say that you do not know the answer. The questions are asked to help the Food Safety Inspectors determine how to inspect your facility under the Preventive Control Rules for Human Food regulations, and to what extent you must comply with those regulations.

For purposes of the FSMA regulation, businesses are put into three categories:

- 1. *Very Small Businesses:* firms with less than \$1 million in sales (3 years average). Firms under this category are considered qualified facilities and they may be eligible for modified requirements.
- 2. *Small Businesses:* firms with less than 500 full-time equivalent (FTE) employees (and over \$1 million in sales).
- 3. *Other Businesses (Large):* firms that do not meet either of the above category criteria (they have 500 or more FTE employees AND have over \$1 million in yearly average sales).

Very small and small businesses processing honey – a low risk food - on their farm where the honey was produced will most likely be exempt from the full requirements of the Preventive Control Rule for Human Food (PC Rule). The exemption in this case includes a waiver from the following:

- Subparts C and G of the PC rule (for small businesses). No need to establish and implement a comprehensive food safety risk-based preventive controls plan including supply-chain program and a recall plan. However, firms are still subject to the good manufacturing practice regulations (GMPs) as set forth is 21 CFR 117 Subpart B (modernized GMPs). Additionally, they may be subject to Subpart D (modified requirements for qualified facilities).
- Subparts C, G, and D of the PC rule (for very small only). Firms under this category are exempt from the PC rule. However, they are still subject to GMPs.

A business that meets the definition of a "qualified facility" (this includes on-farm small honey processor) is subject to modified requirements of the preventive controls rule (Subpart D).

For more information and guidance on Qualified Facility Attestation, visit the FDA website at: https://www.fda.gov/food/guidanceregulation/foodfacilityregistration/qualifiedfacilityattestation/default.htm

For more information about FSMA PC rule, assistance to industry, fact sheets, Training opportunities and more, please visit PDA website at:

http://www.agriculture.pa.gov/consumer protection/FoodSafety/Pages/FSMA-Preventative-Controls.aspx

For training opportunities through Penn State, visit their website at: Penn State Dept of Food Sciences

FDA FSMA information can be found at:

http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm

16. How does the Food Safety Modernization Act (FSMA) affect honey houses?

- Honey producers engaging in processing activities that meet the following two criteria:
 - 1) small or very small businesses (see definitions above), AND
 - 2) conducting these activities On-Farm (or farm mixed-type facilities),

are **NOT** subject to the requirements for hazard analysis and risk-based preventive controls (PC rule). Activities may also include other low risk activities/food combinations as listed in the regulations under 21 CFR 117.5(g) and (h) (e.g. jams/jellies, non-TCS baked goods, dry mixes, maple syrup, etc.).

- All other honey producers that do not meet either of the above two criteria will need to comply with at least some portion of the Preventive Controls Rule.
- Very Small Off-Farm businesses may be eligible as "qualified facilities" for preventive controls modified requirements while <u>Small and Large Off-Farm</u> businesses may be subject to the full requirements for establishing and implementing a comprehensive Food Safety risk-based preventive controls plan.
- Updated Good Manufacturing Practices (cGMPs)

The PC rule under Subpart B in 21 CFR 117 updated the good manufacturing practice requirements. All businesses (regardless of exemption status) are subject to these requirements. The new updates include:

- a) <u>Training:</u> Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties. The employees must be trained in the principles of food hygiene and food safety, including the importance of employee health and hygiene as appropriate to the food, the facility, and the individual's assigned duties. Records of training must be maintained.
- b) <u>Allergen cross-contact</u>: Allergen cross-contact is now explicit in the regulatory text. You are required to employ practices and procedures to control allergen cross-contact.
- c) <u>Human food by-products used for animal foods:</u> The updated GMPs contains provisions for holding and distributing human food by-products that are used for animal food.

For more information and guidance, please visit PDA website at: http://www.agriculture.pa.gov/consumer_protection/FoodSafety/Pages/FSMA-Preventative-Controls.aspx

17. Interested in more information about the Food and Drug Administration (FDA)?

Go to their website at www.fda.gov and click on "Food" (found in the top menu bar). The menu on the right side of the next page will offer several information including but not limited to "Popular Topics", "Food Safety", "Food Businesses", "How to start a Food Business", and "Contact FDA".

FSMA Act amended section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), in relevant part, to require that facilities engaged in manufacturing, processing, packing, or holding food for human consumption in the United States register their facilities with FDA.

To access FDA guidance and regulatory information with links to Federal Register documents and other information about food safety programs, manufacturing processes, industry systems, and import/export activities, visit https://www.fda.gov/Food/GuidanceRegulation/default.htm

Questions for Food Safety?

Please contact:

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with help and guidance from **Food Safety Staff**

This information is designed as guidelines. Please contact Food Safety for additional information.